



PCT/GB 2003 /

REC'D 24 APR 2003

WIPO PCT

**INVESTOR IN PEOPLE**

**The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ**

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

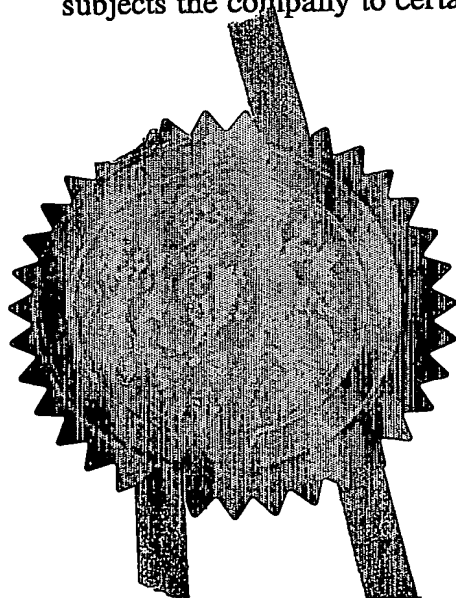
**PRIORITY
DOCUMENT**

SUBMITTED OR TRANSMITTED IN
COMPLIANCE WITH RULE 17.1(a) OR (b)

Signed

McKenzie

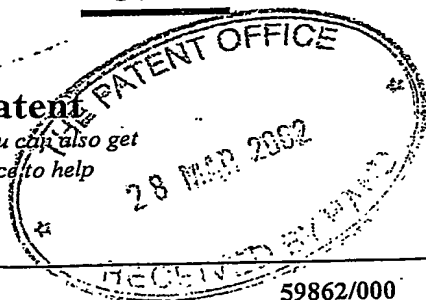
Dated 12 March 2003



Patents Act 1977
Rule 16)

Request for grant of a patent

See the notes on the back of this form. You can also get
an explanatory leaflet from the Patent Office to help
you fill in this form)



30MAR02 E707585-1 D02882
P01/7700 0.00-0207452.4

The Patent Office

Concept House
Cardiff Road
Newport
South Wales NP10 8QQ

1. Your reference

59862/000

2. Patent application number
(The) **0207452.4**

28 MAR 2002

3. Full name, address and postcode of the or of
each applicant (underline all surnames)

BIOQUELL UK LIMITED
WALWORTH ROAD
ANDOVER
HAMPSHIRE
SP10 5AA

Patents ADP number (if you know it)

If the applicant is a corporate body, give the
country/state of its incorporation

UK

8070930001

4. Title of the invention

GASEOUS ROOM DECONTAMINATION

5. Name of your agent (if you have one)

BOULT WADE TENNANT

"Address for service" in the United Kingdom
to which all correspondence should be sent
(including the postcode)

VERULAM GARDENS
70 GRAY'S INN ROAD
LONDON WC1X 8BT

Patents ADP number (if you know it)

42001

6. If you are declaring priority from one or more
earlier patent applications, give the country and the
date of filing of the or of each of these earlier
applications and (if you know it) the or each
application number

Country

Priority application number
(if you know it)

Date of filing
(day/month/year)

7. If this application is divided or otherwise derived
from an earlier UK application, give the number
and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant
of a patent required in support of this request? **yes**
(Answer 'Yes' if:
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

Patents Form 1/77

Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

Description 6

Claim(s) 1

Abstract

Drawing(s) 2

ay

10. If you are also filing any of the following, state how many against each item.

Priority documents n

Translations of priority documents n

Statement of inventorship and right to grant of a patent (Patents Form 7/77) n

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents n
(Please specify)

11

I/We request the grant of a patent on the basis of this application.

Signature

Date

28 March 2002

12.

Name and daytime telephone number of person to contact in the United Kingdom

Geoffrey C Bayliss
020 7430 7500

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

- If you need help to fill in this form or you have any questions, please contact the Patent Office on 01645 500505.
- Write your answers in capital letters using black ink or you may type them.
- If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.
- If you have answered 'Yes' Patents Form 7/77 will need to be filed.
- Once you have filled in the form you must remember to sign and date it.
- For details of the fee and ways to pay please contact the Patent Office.

GASEOUS ROOM DECONTAMINATION

The present invention relates to methods and apparatus for sterilizing the interior surfaces of a room and the surfaces of the contents of the room.

5 For sometime hydrogen peroxide and other gases have been used for the decontamination of the interior surfaces of isolators. This technology has been well established and is covered by numerous Patents such as EP 0486623 BI, UK Patent 2217619B, WO 89/06140 and UK Patent 2308066A.

10 Whilst this technology has worked well in relatively small chambers, up to about 50m³, it has been difficult to achieve fast and reliable decontamination cycles in larger chambers or rooms. This, in fact, has been due to a misunderstanding of the process and hence a difficulty in achieving proper controls. UK Patent Publication No. 2 354443 A describes a new type of gas generator which is more suitable for use in large applications and a further UK Patent Publication No. 236045.4 describes a method of controlling the process by measuring the critical parameters. But
15 neither of these patents addresses the problem of the considerable variation in conditions that are found within a room during the decontamination process

20 Recent research and analysis of the published data shows that for most apparently gaseous decontamination processes, the deactivation of micro-organisms on the surface is achieved by a fine layer of condensation. It follows that to optimise the process it is necessary to not only achieves an even layer of condensation, but also
25 to have sufficient instrumentation to measure the condensation.

An analysis of the paper of Dorothy M Porter and Robert K Hoffman (Applied Microbiology Nov 1988, p 1782-1785) shows that for a mixture of peracetic acid, hydrogen peroxide, acetic acid, sulphuric acid and water, that kill of the test
30 organisms occurred once dew point had been reached. Porter et al reported that kill started when the RH had reached 40%, but this failed to take account of the affect on the dew point of the other liquids present. By using Raoult's Law it is a simple matter to show that dew point for the mixture concerned occurred at about 40% of the saturated vapour pressure of pure water.

35 The difficulty in predicting the dew point for mixtures of hydrogen peroxide, water and other substances is that the vapour pressure is dependent on temperature and the activity coefficients that must be inserted into Raoult's Law. The activity coefficients are also temperature and concentration dependent. It is therefore

difficult, if not impossible, to predict the point at which condensation will occur.

5 Since it is also believed that it is not only the mass of condensate that is important but also the rate of formation of the condensate that is important, it therefore becomes even more difficult to predict the point in a decontamination cycle when deactivation will occur. It has been shown experimentally that some organisms, especially those that contain catalase, are able to decompose the hydrogen peroxide condensation as it forms. However, if the rate of deposition of the hydrogen peroxide condensate is sufficiently high then the catalase is overwhelmed and is unable to decompose the hydrogen peroxide.

10 To overcome these difficulties when decontaminating large volumes it is necessary firstly to ensure a sufficiently high rate of formation of condensation and secondly to be able to measure and control the level of condensation.

15 This invention provides a method of decontaminating an enclosed spaced comprising adjusting the relative humidity within the space to a predetermined level, evaporating a liquid sterilant in the space until the dew point of the sterilant gas is reached and a requisite level of condensation has been deposited on surfaces within the enclosed space, maintaining the level of the condensation for a 20 predetermined period of time and then removing the gas and condensation from the enclosed space; wherein in that condensation is measured within the enclosed space at a number of locations to ensure that condensation takes place throughout the enclosed space.

25 Preferably, condensation is measured at least those locations where the condensation level within the enclosed space is a minimum to ensure that condensation takes place throughout the enclosed space.

30 It is also preferred that sterilant gas is generated from a number of sources within the enclosed space.

35 In one embodiment of the invention, the measurement of condensation at the different locations is arranged to control the production of sterilant gas from the gas generators.

In the latter method the gas generators are controlled by a control system which is responsive to the measuring of condensation at different locations within the enclosure.

Achieving a high rate of formation of condensation on all surfaces requires firstly a high level of evaporation of the decontaminant but of greater difficulty and equal importance is to ensure as near as possible an even layer of condensation on all surfaces. Should preferential condensation form on any surface within the room it follows that a lower rate of formation must be occurring on other surfaces. Since the kill is dependent not only on the mass but also the rate of formation then preferential condensation will have an adverse affect on the decontamination time.

It has further been established that faster rates of deactivation may also be achieved by using mixtures of gases or liquids. S.S. Block in the fifth edition of "Disinfection, Sterilisation and Preservation" page 196 published by Lippincott Williams and Wilkins shows that there is a strong synergistic affect between hydrogen peroxide and peracetic acid. A similar affect was demonstrated by A. Bardat et al and reported in PDA Journal Vol. 50 No. March - April 1996 83-88. The present invention is intended not only to be used with hydrogen peroxide but also with any mixture of liquids that may be flash evaporated and then allowed to condense on the surfaces within the space to be decontaminated.

The equipment comprises one or more devices that will generate a vapour or mixture of vapours, and may be placed inside the space to be decontaminated. Also placed inside the room are a number of sensors, the number depending on the size and shape of the room, to detect the formation of condensation.

The vapour generators and the sensors will be connected to a central control system that will manage all aspects of the decontamination cycle.

Each generator consists of a HEPA filter through which room air is drawn. The air is then heated and passed over a flash evaporation plate where the liquid or mixture of liquids is evaporated into the heated air stream. The hot air carrying the flash evaporated liquid is then directed into the space to be decontaminated at high velocity, preferably by a nozzle or set of nozzles that is rotating in order to achieve good distribution of the gas before it cools and condenses.

For large enclosures it will be necessary to have multiple generators. Firstly, because for mobile equipment the available electrical power is limited and secondly, the jet of hot gas produced by each generator will only reach a limited distance before it loses its kinetic energy and cools. When a number of generators are required these will be linked together to the central control together with the condensation monitors.

A decontamination cycle for a room is in four phases. The first is conditioning, during which all of the equipment is allowed to come to thermal stability and the Relative Humidity (RH) inside the volume is brought to the required starting value. During the second phase the liquid sterilant is evaporated by the gas generators, first raising the gas concentrations to dew point, and then depositing the required level of condensation.

In the third phase the level of condensation is maintained for a sufficient length of time to achieve the required degree of decontamination. For some installations this phase may be omitted if a satisfactory deactivation is guaranteed in phase two. The fourth and final phase is the removal of the gas and condensation from the room.

Further equipment will be required, apart from the gas generators and condensation monitors to achieve the above cycle.

During the first phase it may be necessary to dehumidify the room. Using the room HVAC system, or alternatively by having a mobile dehumidifier may do this. A dehumidifier using a chemical dryer would be suitable for this application. The removal of the gas in phase four of the cycle may be achieved by using the HVAC system, but if this is not practical then a portable catalytic converter may be used. Such devices consist of a fan, which drives air first through a catalytic converter and then a HEPA filter.

The catalytic converter renders the gases harmless and the HEPA filter removes the viable and non-viable particles from the air stream.

The following is a description of some specific embodiments of the invention, reference being made to the accompanying drawings in which:-

Figure 1 is a diagrammatic view of a sterilant gas generation apparatus; and Figure 2 is a diagrammatic view of a room to be decontaminated containing a plurality of sterilant gas generators and control system to controlling the decontamination process.

A gas generator 10 is shown in Figure 1. Air is drawn in through a HEPA filter 11 by a fan 12 and passed into a vaporiser 13. Inside the vaporiser the air is first heated by aheater (not shown) and then passes over an evaporation plate (also not shown) A pump 15 delivers liquid sanitant from a sanitant bottle 16 in the form of droplets onto the evaporation plate from which it is flash evaporated. The heated

air carrying the sanitant vapour is passed to a distribution plenum 18 and exits to the room at high velocity through one or more nozzles 19 .

5 Provision is made either to connect a number of optical type condensation monitors 20 directly to the gas generator and hence to a control module 21 (see Figure 2), or the monitors may be connected directly to the control module. The optical condensation monitors measure the layer of condensation as it builds up on a surface or surfaces of the monitor. Connecting condensation monitors to the gas generator has the advantage of reducing the number of connections to the control module, especially when a number of gas generators are used.

10 The condensation monitors are placed around the room at the locations where the rate of condensation is the lowest.

15 A complete multiple installation is shown in Fig 2, with three gas generators, 10 each with eight condensation monitors 20. Also connected to the control system is an aeration unit 22 used to remove the gas at the end of the cycle and the dehumidifier 23. A separate instrument module 24 is also shown which has additional instrumentation to measure the gas concentration and the RH within the room. A single communications cable connects 24 all of the components to the control module.

25 The normal technique to establish if a decontamination process has been successful is to place Biological Indicators (BIs), in those parts of the chamber where it is the most difficult to achieve a kill. It is often undesirable or not permitted to place BIs in a room, but it is necessary to know that deactivation to the required level has been achieved. To overcome this difficulty condensation monitors may be used to establish that the mass and the rate of formation of condensate are sufficient to achieve deactivation of the microorganisms on the surfaces. It has been well established that once the required conditions have been achieved that the "D" value for the most resistant organisms is about two minutes. Therefore an exposure of the organisms under the correct conditions for twelve minutes will achieve a log 6 reduction in the count of viable organisms.

35 Satisfactory decontamination will only be achieved in a room if a sufficiently high rate of liquid sanitant vapour is delivered into the room to provide an adequate rate of formation of condensation. But to be assured that decontamination has been achieved it is necessary to measure the condensation levels with time in multiple locations in the room. The data from the condensation monitors together with the

information from the other instruments in the room may then be used to establish that a satisfactory deactivation cycle has been completed.

5 The condensation sensors may be used in one of two ways. The first is to measure and then control the level of condensation by adjusting the liquid evaporation rate and the second is simply to use the monitor as a switch. When used as a switch it simply gives a signal when an adequate amount of condensation has formed and the process is then considered to be complete or allowed to dwell in that state giving a sufficient period during which the organisms are killed. There is a further variation to the "switch" method in which two sensors are used at each location set at different levels of condensation. The first indicates when condensation has started and the second when the level of condensation is sufficient to have caused a satisfactory level. It may then be necessary to have a "dwell" period during which the kill occurs.

15 The condensation monitors of the above apparatus are optical devices which measure the layer of condensation. An electronic device may be used instead that gives a switch signal when a known level of condensation has arrived. The switch level depends on the construction of the sensor plate. Sensor plates are single use disposable items and hence are inexpensive. The plates plug into a box which may be placed at a remote location within the room.

CLAIMS

5 1. A method of decontaminating an enclosed spaced comprising adjusting the relative humidity value within the space to a predetermined level, evaporating a liquid sterilant in the space until the dew point of the sterilant gas is reached and a
10 requisite level of condensation has been deposited on surfaces within the enclosed space, maintaining the level of the condensation for a predetermined period of time and then removing the gas and condensation from the enclosed space; characterised in that condensation is measured within the enclosed space at a
number of locations to ensure that condensation takes place throughout the enclosed space.

15 2. A method as claimed in claim 1, wherein condensation is measured at least those locations where the condensation level within the enclosed space is a minimum to ensure that condensation takes place throughout the enclosed space.

20 3. A method as claimed in claim 1 or claim 2, wherein sterilant gas is generated from a number of sources within the enclosed space.

25 4. A method as claimed in claim 3, wherein the measurement of condensation at the different locations is arranged to control the production of sterilant gas from the gas generators.

30 5. A method as claimed in claim 4, wherein the gas generators are controlled by a control system which is responsive to the measuring of condensation at different locations within the enclosure.

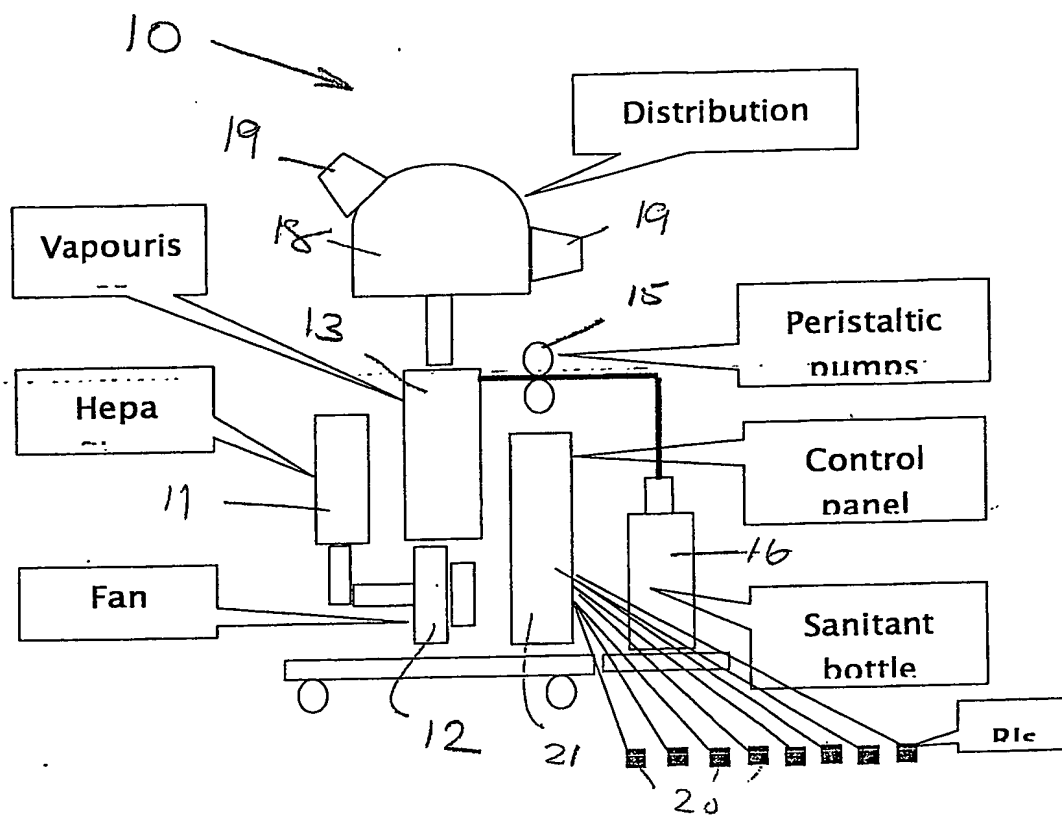


Fig 1

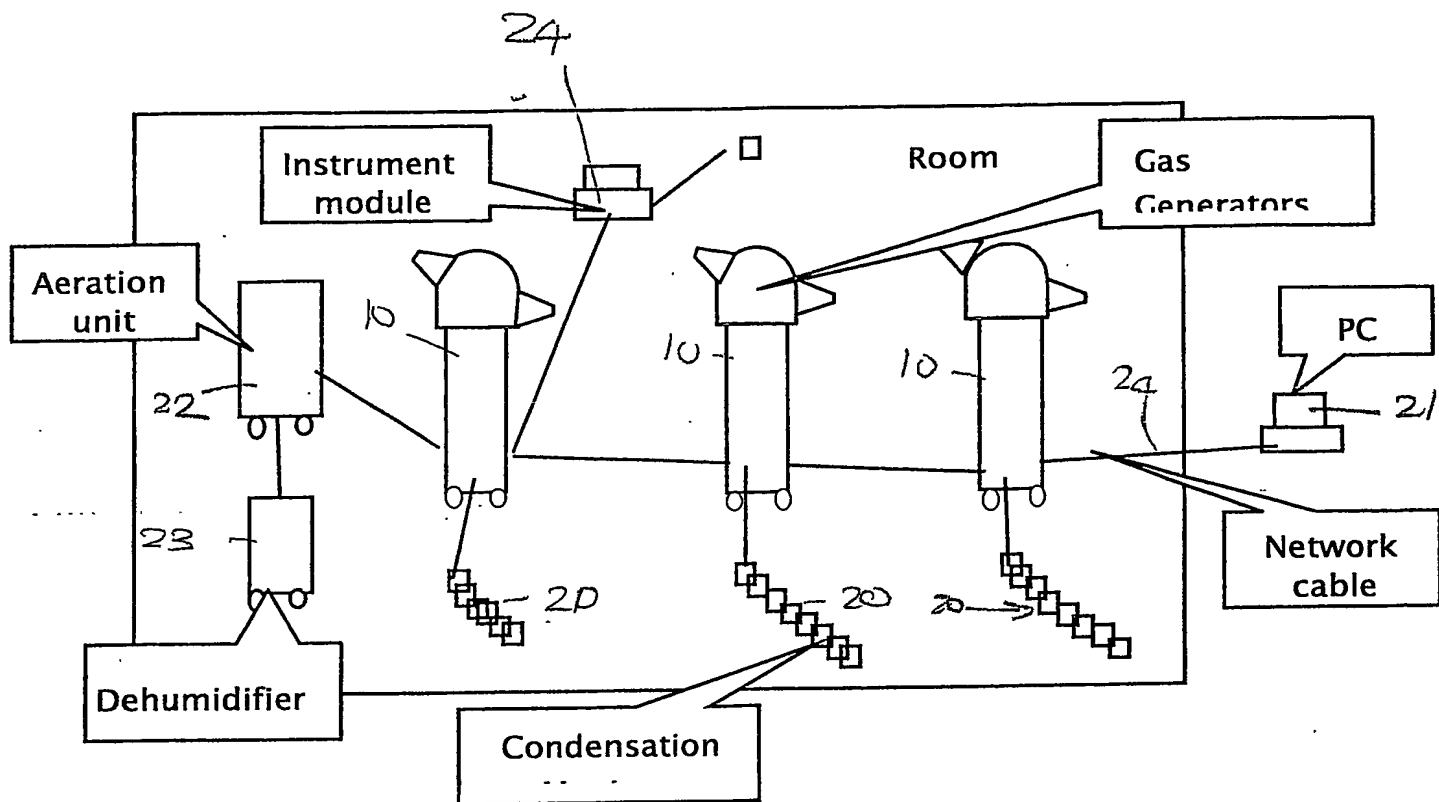


Fig 2